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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/913,671	09/24/2001	Antonio Parente Duena	P/189-162	4516

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OSTROLENK FABER GERB & SOFFEN
1180 AVENUE OF THE AMERICAS
NEW YORK, NY 100368403

EXAMINER
YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 07/21/2003 16

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	
Office Action Summary	09/913,671	DUENA ET AL.	
	Examiner	**Art Unit**	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Acknowledgment of Papers Received: Request for Extension of Time and Request for Continued Examination dated 5/2/03.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by BIOGRAM AM (WO 97/14408). The claims are drawn to a pharmaceutical preparation comprising lactic-co-glycolic copolymer, which incorporates a peptide, and a citric acid ester.

BIOGRAM AM discloses a microcapsule comprising PLGA (poly lactic/glycolic acid) comprising proteins, and peptides and triethyl citrate as an additive (pg.8, lin. 1-14; pg. 10, lin. 29 – pg. 11, lin. 10, claims). These disclosures along with others render the claims anticipated.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over BIOGRAM AB (WO 97/14408). The claims are drawn to a microcapsule formulation comprising a peptide, lactic-co-glycolic acid and a citric acid ester. The claims recite concentrations of the citric acid ester and proportions for the lactic acid and glycolic acid in the copolymer.

BIOGRAM discloses general formulation comprising PLGA and triethyl citrate as an additive. The reference is lacking specific teachings to the concentrations of the citric acid esters and the proportions of the copolymer acids. However it has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various pharmaceutical compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With this in mind it would have been obvious to one of ordinary skill in the art to maximize the concentrations and proportions of the formulations of BIOGRAM in order to

deliver the optimum formulation and improve the delivery of the bioactive agent. It would have been obvious to a skilled artisan to follow the suggestions of the art and maximize and optimize the concentrations of citric acid ester and copolymer with an expected result of a pharmaceutical formulation useful in delivering peptides and proteins to treat disorders.

6. Claims 6 – 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over BIOGRAM AB (WO 97/14408) in view of Yamamoto et al (USPN 4,954,298), Bodmer et al (USPN 5,538,739) and Canal et al (USPN 5,536,508). The claims are drawn to a pharmaceutical dosage form comprising lactic-co-glycolic copolymer, a citric acid ester and various species of peptides.

As discussed above BIOGRAM discloses a microcapsule formulation comprising lactic-co-glycolic acid copolymer, triethyl citrate, and various peptides and proteins. The reference however does not disclose the specific species of peptides, though the reference suggests the inclusion of peptides into the formulation. It would be well within the level of skill in the art to include these species into the formulation of BIOGRAM.

Yamamoto et al teaches essential elements of claims 5-7. The reference teaches a microcapsule sustained-release formulation comprising a biodegradable copolymer of lactic/glycolic acid, and a LHRH derivative, leuprolide (Abstract; column 2, lines 28-32; Examples 2, 4 and 5). The reference also teaches the concentrations of the claimed invention for the lactic/glycolic copolymer (column 5, lines 26-36).

Bodmer et al teaches essential elements of claims 5, 8 and 9. The reference teaches a microcapsule sustained-release formulation comprising a biodegradable copolymer of lactic/glycolic acid, and a somatostatine analogue, octreotide (Abstract; column 4, lines 18-25; Examples; claims1-5).

Canal et al teaches essential elements of claims 5, 10 and 11. The reference teaches a microcapsule sustained-release formulation comprising a biodegradable copolymer of lactic/glycolic acid, and a calcitonine analogue, salmon calcitonine (Abstract; column 4, lines 30-36; Examples 15 and T).

These references disclose specific peptides in combination with lactic/glycolic acid copolymers and would be suitable to be included in the formulations of BIOGRAM. One of ordinary skill in the art would have been motivated to include these compounds under the suggestion of BIOGRAM and the individual references. BIOGRAM discloses the inclusion of peptides, while the references disclose the peptides in lactic/glycolic copolymer formulations. A skilled artisan would have been motivated to make the substitutions in order to impart particular prophylactic properties onto the formulation of BIOGRAM. It would have been obvious to combine the references with an expected result of a microcapsule formulation useful for the treatment of various disorders.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young
July 16, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER